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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,016	03/23/2004	David Feygin	115-004US	4798

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EXAMINER	
CRABTREE, JOSHUA DAVID	
ART UNIT	PAPER NUMBER
3714	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/807,016	FEYGIN ET AL.	
	Examiner	Art Unit	
	Joshua D. Crabtree	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-40 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/23/04,6/23/05,10/23/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Pugh (US 2003/0031993).

With regard to claim 1, and the limitations of a pseudo skin, and a receiver, wherein the receiver receives an end effector, Pugh discloses an anatomical simulator with a simulated surface, with one or more sensors in the anatomical simulator (Paragraph [0011]). With regard to the limitation of a first device for performing a first skin-interaction technique, wherein the receiver and first device are disposed beneath the pseudo skin, Pugh discloses that the simulator may include anatomical parts inside, such as a spleen or liver (Paragraph [0013]). The simulated parts may be used for simulating palpation or manual assessment by a user (Paragraph [0012]). Therefore, the end effector could comprise a user's hand.

With regard to claim 2, and the limitation wherein an insertion region for the end effector is defined at a site at which the end effector is received by the receiver, and wherein the insertion region is proximal to a first region of the pseudo skin, Pugh

discloses that openings may be used so that a user may access internal organs (Paragraph [0012]; Figs. 14A-C, 15, and 16).

With regard to claim 3, and the limitation wherein the first-skin interaction technique comprises at least one of either palpation or occlusion, Pugh discloses that a user may perform palpation or manual assessments (Paragraph [0012]). With regard to the limitations wherein a second region of the pseudo skin is accessible to perform the first skin-interaction technique, and wherein the first region of the pseudo skin is closer to a user than the second region of the pseudo skin when the user is using the apparatus, Pugh discloses that the anatomical simulator may have multiple regions, such as an anterior and posterior region (Paragraph [0041 - 0042]; Fig. 3). One region would be closer to a user then another region, depending on the location of the user with respect to the apparatus.

With regard to claims 4 and 13, and the limitation of a second device for performing a second skin-interaction technique, wherein the second device is disposed beneath the pseudo skin, Pugh discloses that a plurality of simulated organs may be included so that different types of examinations may be performed (Paragraph [0012]).

With regard to claim 5, and the limitation wherein the skin-interaction technique comprises skin stretching, Pugh discloses skin stretching in Figs. 14C, 15, and 16. With regard to the limitation wherein a third region of said pseudo skin is accessible to perform the second skin interaction, and wherein the third region of the pseudo skin is closer to a user than the first region of the pseudo skin when the user is using the

apparatus, Pugh discloses that a plurality of regions of skin may be used for performing assessments (Fig. 15-17). One region would be closer to a user then another region, depending on the location of the user with respect to the apparatus.

With regard to claim 6, and the limitation of a housing, wherein the housing has an anterior portion, a posterior portion, an upper surface and a lower surface, Pugh discloses that the simulator may contain anterior and posterior portions, as well as superior and inferior poles (i.e., upper and lower surfaces) (Fig. 3; Paragraphs 0041 - 0042]). Additionally, Pugh discloses various embodiments in which a housing may be used to contain the simulated organs (Figs. 1, 8, 15). Additionally, Pugh discloses various housings which may be used with the invention (Item 18 in fig. 1; Items 33 and 40 in Fig. 4; Item 102 in fig. 8; Fig. 9). Each of the aforementioned housings have anterior and posterior regions, and upper and lower surfaces. With regard to the limitation wherein, in use, the anterior portion is proximal to a user, and the posterior portion is distal to a user, a user of the invention of Pugh could be closer to one portion then another, depending on the location of the user with respect to the apparatus. With regard to the limitation wherein the lower surface is proximal to a support surface on which the apparatus resides, and wherein the upper surface is distal to the support surface, Pugh discloses this feature in Fig. 8, which shows the apparatus resting on a support surface 104, wherein the lower surface of the apparatus is proximal to the support surface, and the upper surface of the apparatus is distal to the support surface (Paragraph [0056]).

With regard to claim 7, and the limitation wherein the upper surface is no more than about 5 inches above the lower surface, the housing units 33 and 40 in Fig. 4 appear to have only a slightly bigger height than the mouse 44. Since a mouse is generally about 1.5 inches high, one could assume that housings 33 and 40 in Fig. 4 are probably about 2 or 3 inches high. Additionally, Pugh discloses that the size of the anatomical simulator and organs represent expected ranges of human size, shape, and other qualities (Paragraph [0038]). Therefore, if the invention were being used to simulate the anatomy of a baby or small child, the height of the anatomical simulator would be less than about 5 inches.

With regard to claim 8, and the limitation wherein the housing comprises at least one opening proximal to the upper surface thereof to access the pseudo skin, Pugh discloses a plurality of openings through which a user may interact with the simulator (Figs. 14A-C, 15, and 16).

With regard to claim 9, and the limitation wherein the housing comprises a handle proximal to the anterior portion by which a user grips the apparatus during use, Pugh discloses appendages which may be used to grab by a user (*Fig. 8 shows two such appendages at the rightmost portion of the drawing*).

With regard to claim 10, and the limitation wherein an insertion region for the end effector is defined at a site at which the end effector is received by the receiver, and wherein the insertion region is proximal to a first region of the pseudo skin, Pugh discloses an insertion region for a user's hand (i.e., end effector) (Fig. 15). With regard to

the limitation wherein a first end of the receiver is relatively closer to the insertion region and a second end of the receiver is relatively further from the insertion region, Pugh discloses that tactile sensors may be located in the simulator to detect user interaction with the organs (Paragraph [0011], [0013 - 0015]). The tactile sensors may be located at various positions with regard to a simulated anatomy, including the outer surface and inner cavity (Items 16 and 20 in Fig. 1; Paragraph [0037]). Therefore, one sensor (i.e., a first end of the receiver) could be located close to an insertion region, while another sensor (i.e., second end of the receiver) could be located underneath an organ, farther away from the insertion region than the first sensor.

With regard to claims 11, 12, and 14, and the limitation wherein the first skin interaction technique comprises at least one of either palpation or occlusion, Pugh discloses this feature, as previously described (Paragraph [0012]).

With regard to claim 11, and the limitation wherein the first end of the receiver is closer to the anterior portion of the housing than the first device, Pugh discloses that tactile sensors may be placed at various locations with regard to a simulated organ (i.e., first device) (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]). Therefore, depending on the chosen location for a sensor, the sensor could be closer to the anterior portion of the housing than the organ.

With regard to claims 12 and 18, and the limitation wherein an upper-most surface of the first device extends a greater distance above the lower surface of the housing that the first end of the receiver, the tactile sensors of Pugh may be smaller than

a simulated organ (i.e., first device), and may be placed at various locations with regard to the organ (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]). Therefore, a sensor placed on the side of an organ would be a shorter distance from the lower surface of the housing than the upper-most surface of the organ (See also Fig. 2).

With regard to claim 15, and the limitation wherein at least some portion of the second device is closer to the anterior portion of the housing than the first device, Pugh discloses that a plurality of different simulated organs (i.e., devices) may be used in the simulator, as previously described (Paragraph [0012]). Therefore, one organ, such as the liver, would be closer to the anterior portion of the simulator than another organ, such as a heart or brain.

With regard to claim 16, and the limitation wherein at least some portion of the second device is closer to the anterior portion of the housing than the first end of the receiver, Pugh discloses that tactile sensors (all of which would comprise a receiver) may be placed at various locations with regard to a simulated organ (i.e., first device), as previously described (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]). Therefore, the location of a second organ (i.e., second device) could be closer to the anterior portion of the housing than a sensor (i.e., first end of the receiver), depending on the chosen location for the sensor.

With regard to claim 17, and the limitation wherein the first end of the receiver is closer to the anterior portion of the housing than the first device, Pugh discloses that

tactile sensors may be placed at various locations with regard to a simulated organ (i.e., first device), as previously described (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]). Therefore, a sensor could be placed closer to the anterior portion of the housing than an organ (i.e., first device), as chosen by a user.

With regard to claim 19, and the limitation wherein an upper-most surface of the first device extends further above the lower surface of the housing than an upper-most surface of the second device, Pugh discloses that various simulated organs (i.e., devices) may be used in the simulator, as previously described. Therefore, a certain organ (such as a kidney) would be further from the lower surface of the housing than another organ, such as heart, depending on the orientation of the simulator (See Fig. 8).

With regard to claim 20, and the limitation wherein at least a portion of the receiver is disposed beneath an upper-most surface of the first device, Pugh discloses that tactile sensors may be placed at various locations with regard to a simulated organ (i.e., first device), as previously described (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]).

With regard to claim 21, and the limitation of an electronics/communications interface, wherein the electronics/communications interface receives signals from sensors that are associated with at least one of the first device or the receiver, and wherein the electronics/communications interface is disposed beneath the pseudo skin, Pugh discloses that signals are sent from the sensors to a computer (Paragraph [0014 -

0017]). Pugh discloses that the signals may be received via wires that are located inside the simulator (i.e., beneath the pseudo skin).

With regard to claims 22 and 23, and the limitation wherein the electronics/communications interface is closer to the posterior portion of the housing than the first device (as in claim 23), and wherein the electronics/communications interface is closer to the posterior portion of the housing than the receiver (as in claim 24), the invention of Pugh is inherently capable of this feature, since one of the simulated organs (i.e., a first device) or a sensor (i.e., receiver) could be located further from the posterior of the housing than the wires connected to the sensors.

With regard to claim 24, and the limitation wherein the electronics/communications interface comprises a printed circuit board, and further wherein a major surface of the printed circuit board is disposed orthogonal to an uppermost surface of the first device, Pugh discloses that a breadboard may be part of the communications interface (Paragraph [0045]; Item 33 in Fig. 4). Additionally, Pugh discloses that a computer may be part of the communications interface (Item 34 in Fig. 4). Printed circuit boards (such as the motherboard and expansion cards) are inherently part of a computer. The orientation of the circuit boards, with respect to a specific simulated organ (i.e., first device) would depend on where a user of the invention chooses to place them. Therefore, a user could place one of the circuit boards orthogonal to a surface of an organ.

With regard to claim 25, and the limitations of a housing and an end effector, wherein the end effector is inserted into the hosing during the performance of a simulated vascular access procedure, Pugh discloses an anatomical simulator (i.e., housing) as previously described. End effectors may include a user's hand, a needle, or other devices (Paragraph [0062]; Figs. 14A-C, 15, and 16). Pugh discloses that any type of surgical procedure including a component which must be performed manually or inside an anatomical space and involving an organ or body surface may be taught with the invention (Paragraph [0062]).

With regard to the limitation of a plurality of mechanisms, wherein the plurality of mechanisms are contained completely within the housing, and wherein the plurality of mechanisms include a first mechanism for simulating a first skin-interaction technique, and a second mechanism for receiving the end effector, Pugh discloses that simulated organs (i.e., mechanisms) may be located inside the simulator, which may be used to simulate palpation, as previously described (Paragraph [0012]). Pugh discloses that tactile sensors (i.e., mechanisms for receiving the end effector) which sense a user's interactions with the simulated organs (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]).

With regard to claim 26, and the limitations wherein the housing has a longitudinal axis, a first end of the longitudinal axis defines an anterior portion of the housing, a second end of the longitudinal axis defines a posterior portion of the housing, and in use, the anterior portion is proximal to a user and the posterior portion

is distal to the user, Pugh discloses that the simulator may resemble a portion of a human body, which would include anterior and posterior regions, as defined by the regions spatial relationship with respect to a longitudinal axis (See Fig. 1 and 8). The proximity of a region with respect to a user would depend on the user's desired location when working with the invention. Therefore, a user could stand closer to the posterior region than the anterior, if the user went to that location.

With regard to claim 27, and the limitation wherein the plurality of mechanisms are disposed beneath a pseudo skin, Pugh discloses that the sensors and simulated organs (i.e., mechanisms) may be located within the simulator (i.e., underneath the pseudo skin) (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]).

With regard to claim 28, and the limitation wherein the mechanisms include a third mechanism for simulating a second skin-interaction technique, and wherein the end effector is at least one of either a needle or a catheter, Pugh discloses that a breast (i.e., third mechanism) may be used with an effector such as a needle (Paragraph [0062]).

With regard to claims 29-33, and the limitations wherein the first skin-interaction technique is skin-stretch, and the second skin-interaction technique is at least on of either palpation or occlusion, Pugh discloses that skin stretching (Figs. 14C, 15, and 16) and palpation (Paragraph [0012]) may be performed, as previously described.

With regard to the limitation wherein at least a portion of the first mechanism is disposed at a substantially different position along the longitudinal axis than the second mechanism and third mechanism (as in claim 29), and wherein the first mechanism is closer to the anterior portion of the housing than the second mechanism and third mechanism (as in claim 30), and wherein at least a portion of the second mechanism is disposed at a substantially different position along the longitudinal axis than the first mechanism and third mechanism (as in claim 31), and wherein the third mechanism is closer to the posterior portion of the housing than the first mechanism and second mechanism (as in claim 32), and wherein the portion of the second mechanism is flanked by the first mechanism and the third mechanism along the longitudinal axis (as in claim 33), Pugh discloses that a tactile sensor (i.e., second mechanism) may be placed at various locations with regard to simulated organs (i.e., first and third mechanisms), as previously described (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]). Therefore, a first organ could be located substantially differently along the longitudinal axis of the simulator, in relation to the locations of a sensor (i.e., second mechanism) and another organ (i.e., third mechanism), as recited in claim 29. Similarly, the locations of the sensor and organs could be located according to the arrangements recited in claims 30-33, as desired by a user.

With regard to claim 34, and the limitation wherein a user interacts with the first mechanism at a first site at an upper surface of the housing, and wherein the user

interacts with the second mechanism at a second site at the upper surface of the housing, and wherein the user interacts with the third mechanism at a third site at the upper surface of the housing, Pugh discloses that a user may interact with a plurality of simulated organs (i.e., mechanisms) via a plurality of openings on the simulator (Figs. 14A-C, 15, and 16).

With regard to claim 35, Pugh discloses a pseudo skin, a plurality of mechanism with which a user interacts for simulating a vascular-access procedure, wherein the plurality of mechanisms are disposed under the skin, and a housing, wherein the housing contains the plurality of mechanisms, as previously described (Fig. 8; 14A-C, 14, 16; Paragraph [0062]).

With regard to claims 36 and 37, and the limitation wherein the housing is no more than about 5 inches in height (as in claim 36), wherein the housing is no more than about 4 inches in height (as in claim 37), Pugh discloses that the size of the anatomical simulator and organs represent expected ranges of human size, shape, and other qualities (Paragraph [0038]). Therefore, if the invention were being used to simulate the anatomy of a baby or small child, the height of the anatomical simulator would be less than about 4 or 5 inches.

With regard to claim 38, and the limitation wherein at least one of either a needle or catheter is disposed outside of said housing until inserted during a simulated vascular access procedure, Pugh discloses that a needle may be used (Figs. 14B-C).

With regard to claim 39, and the limitation of a data processing system, wherein the data processing system receives signals from sensors that are associated with the plurality of mechanisms, Pugh discloses this feature (Fig. 1, 4, 8; Paragraphs [0014 - 0017]).

With regard to claim 40, and the limitation wherein the plurality of mechanisms comprise discrete devices, wherein a first of the devices is for enabling a user to perform a skin stretch technique, a second of the devices is for receiving a needle or catheter or both, and a third of the devices is for enabling a user to perform at least one of either a palpation technique or occlusion technique, Pugh discloses that that the skin of the simulator may be stretched (Fig. 14C, 15, and 17), that an organ may be used to receive a needle (Fig. 14B), and that an organ may be used for palpation (Fig. 14A).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cioppa (US 3,704,529) discloses a training and instruction device for performing cricothyroidotomy.

Adams et al. (US 4,134,218) discloses a breast cancer detection training system.

Eggert (US 5,472,345) discloses a gynecological simulator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joshua D. Crabtree whose telephone number is 571-272-8962. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
Joshua D. Crabtree
March 22, 2007

Joe H. Cheng
Primary Examiner